DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 15, 2015

Gloster Biomedical International
Ms. Catherine Gloster
Founder and Principal Consultant
577 North Hope Avenue
Santa Barbara, California 93110

Re: K142675
Trade/Device Name: CI../..X liner for NOVAE® Dual Mobility Acetabular Cup
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, MEH
Dated: October 20, 2014
Received: October 21, 2014

Dear Ms. Gloster:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K142675

Device Name: CI../..X liner for NOVAE® Dual Mobility Acetabular Cup

Indications For Use:

NOVAE® Dual mobility Acetabular Cup is indicated for total hip replacement, which includes:

- Osteoarthritis
- Femoral neck fracture
- Dislocation risk
- Osteonecrosis of the femoral head
- Revision procedures where other treatments or devices have failed and if bone reconstruction so permits

SUNFIT TH, NOVAE E TH and COPTOS TH are intended for press-fit use and NOVAE STICK is indicated for cemented use.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5

510(k) Summary

Date: January 15th, 2015

Company name and address: SERF
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69153 Décines Cedex
FRANCE
Phone: +33 4 72 05 60 10
Fax: +33 4 72 02 19 18

Contact person: Jean-Luc AURELLE
General Manager / Industrial Manager

Date prepared: July 25th, 2014

Trade name: CI../..X liner for NOVAE® Dual Mobility Acetabular Cup

Common name: Total hip prosthesis – Acetabular component

Classification name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Product Code LZO/MEH)

Device description
The CI../..X liner for NOVAE® Dual Mobility Acetabular Cup is made of cross-linked Ultra-High-Molecular-Weight Polyethylene which meet the strength requirements of the ASTM F648 and the testing listed in the ASTM F2565. The liner is mobile (free) in the NOVAE® metallic shell (clearance K111572) and retained on the prosthetic femoral head.
Liners can be used with ∅22.2 or 28 mm prosthetic femoral heads.

Substantial equivalence claimed to predicate devices
The CI../..X liner for NOVAE® Dual Mobility Acetabular Cup is substantially equivalent to the CI../..E liner for NOVAE® Dual Mobility Acetabular Cup (K111572, SERF) in terms of intended use, design, range of sizes, mechanical safety and performances.
The CI../..X liner for NOVAE® Dual Mobility Acetabular Cup is substantially equivalent to ApeX-LNK Poly™ Acetabular Cup Liner (K100555, OMNIlife science) in terms of intended use, material and manufacturing and sterilization processes.

Device	CI../..X liner for NOVAE® Dual Mobility Acetabular Cup	NOVAE® Dual Mobility Acetabular Cup	ApeX-LNK PolyTM Acetabular Cup Liners
510(k) number	/	K111572	K100555
Intended use			
Total hip replacement	Yes	Yes	Yes
Cementless/ cemented	Yes/Yes	Yes/Yes	Unknown
Primary/ Revision	Yes/Yes	Yes/Yes	Yes/Yes
Design			
Dual mobility	Yes	Yes	No
Liner is retained on the head	Yes	Yes	No
Materials			
Liner	Cross-linked UHMWPE	UHMWPE	Cross-linked UHMWPE

Intended use

CI../..X liner for NOVAE® Dual mobility Acetabular Cup is indicated for total hip replacement, which includes:

- Osteoarthritis
- Femoral neck fracture
- Dislocation risk
- Osteonecrosis of the femoral head
- Revision procedures where other treatments or devices have failed and if bone reconstruction so permits

SUNFIT TH, NOVAE E TH and COPTOS TH are intended for press-fit use and NOVAE STICK is indicated for cemented use

Non-clinical Test Summary

The following tests were conducted:

- Dimensional analysis
- Head insertion force
- Head lever out force
- Wear analysis

Acceptance criteria were met for each test above.

Clinical Test Summary

No clinical studies were performed

Conclusions Nonclinical and Clinical

CI../..X liner for NOVAE® Dual mobility Acetabular Cup is substantially equivalent to the predicate devices in terms of indications for use, design, material, function and performances.